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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,243	08/03/2001	Gavin MacBeath	H00498/70162 TJO	9118

7590

02/24/2003

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EXAMINER

CHEU, CHANGHWA J.

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/24/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

11/14/02

Office Action Summary

Application No.

09/923,243

Applicant(s)

MACBEATH ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 48-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 28-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group II, claims 28-47, with traverse in Paper No. 15 acknowledged. Applicants asserted that it is believed that a single search and examination covering all claims would not place undue burden on the examiner is noted. However, the record clearly indicates that the delineated invention are in fact patentably distinct each from each other. Therefore, groups I, III – VII are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 35, line 2, "linkage is *robust enough* so that the compounds are not inadvertently cleaved," is vague and indefinite. It is unclear as to what constitutes "robust enough" in the claim language.

With respect to claim 35, line 2, "linkage is robust enough so that the compounds are not *inadvertently* cleaved," is vague and confusing. It is unclear what applicants mean "inadvertently". It is suggested that applicants delete the wording "inadvertently" for better clarity.

With respect to claim 35, line 3, "inert so that the *functionality employed* do not interfere with subsequent manipulation steps," is vague and confusing. It is unclear as to what "functionalities" applicants intend to employed after the proteins have been attached to the bovine serum albumin.

Claim Rejections - 35 USC § 102

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 28-41, 43-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Charych et al. (USP 2002/0055125).

Charych et al. teach a protein microarray comprising a solid support coated with BSA and the density spots ranges from about 1 to 5000 spots/ cm². (Page 7, Section 0066, and section 0069, line 5-7) The proteins attached to the BSA are naturally folded and functional. (Section 0057, line 17-20) Charych et al. also teach use either non-covalent or covalent interaction for binding the proteins to the solid support. (Section 0046, line 14; Section 0047, line 4) Furthermore, Charych et al. teach attaching linker for proper cleavage and ensuring not interference with the subsequent protein binding on the reaction surface. (Section 0062, line 7-10; Section 0089, line 1-5) In addition, Charych et al. teach attachment of the proteins with BSA via either Schiff's base linkage, acylation or Michael addition. For instance, suitable covalent interactions include, reacting maleimide with a thio group (forming disulfide bond), aldehyde with Asparagine or lysine residues or peptide bond interacting with another amino acid (transacylation). (Section 0042, line 16-18; Section 0046, line 12-20) Charych et al. also teach attaching BSA with antibodies as a positive control. (Section 126, line 2-6) Although Charych et al do not explicitly indicate the coating of BSA on the array plate is a non-specific interaction for the subsequent binding assay, it is inherent that coating BSA on the solid support serves the purpose to reduce non-specific binding. (See Schultz et al., USP

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6180415, Col. 29, line 27-34) As to the materials for solid support, Charych et al. teach using variety of substances, including glasses, polymer, and metals. (Section 0037, line 17-20) Finally, Charych et al. also teach the solid support at least includes one self-assembled monolayer. (Section 54, line 3)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charych et al. in view of Patron et al. (USP 2001/0041349).

Charych et al's reference has been discussed but fails to specifically teach using poly-histidine-metal interaction as the protein/BSA binding method. Patron et al. teach using poly-histidine tag to bind to metals for purification purpose in a protein microarray. (See Figure 1; Section 0039, line 5-10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the reference

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of Charych et al. with the poly-histidine tag as taught by Patron et al. to increase the purity and reduce the contaminants of the protein microarray.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu



Examiner

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February 19, 2003



LONG M. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

02/21/03